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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/230,929      | 04/02/1999  | JURGEN KLEINSCHMIDT  | 4121-107            | 3634             |

7590 02/12/2002

STEVEN J HULTQUIST  
INTELLECTUAL PROPERTY TECHNOLOGY LAW  
PO BOX 14329  
RESEARCH TRIANGLE PARK, NC 27709

[REDACTED] EXAMINER

WOITACH, JOSEPH T

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1632     | -2 C         |

DATE MAILED: 02/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

|                        |                                      |  |
|------------------------|--------------------------------------|--|
| <b>Advisory Action</b> | Application No.<br><b>09/230,929</b> | Applicant(s)<br><b>Kleinschmidt, J. et al.</b> |
|                        | Examiner<br><b>Joseph T. Woitach</b> | Art Unit<br><b>1632</b>                        |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Feb 6, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**THE PERIOD FOR REPLY [check only a) or b)]**

- a)  The period for reply expires 3 months from the mailing date of the final rejection.
- b)  In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.  A Notice of Appeal was filed on \_\_\_\_\_ . Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2.  The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3.  The proposed amendment(s) will not be entered because:
  - (a)  they raise new issues that would require further consideration and/or search. (See NOTE below);
  - (b)  they raise the issue of new matter. (See NOTE below);
  - (c)  they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d)  they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: See attached.

4.  Applicant's reply has overcome the following rejection(s):  
\_\_\_\_\_  
\_\_\_\_\_

5.  Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).

6.  The a)  affidavit, b)  exhibit, or c)  request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See attached.

7.  The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8.  For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 14-66

9.  The proposed drawing correction filed on \_\_\_\_\_ a)  has b)  has not been approved by the Examiner.

10.  Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

11.  Other:

*Deborah Crouch*  
**DEBORAH CROUCH**  
**PRIMARY EXAMINER**  
 E-mail: [crochde@uspto.gov](mailto:crochde@uspto.gov) Paper No. 20  
 GROUP 1800 1630

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Attachment to Advisory Action:

Section 3(a):

There recitation of ‘the non-transforming ORF’ lacks antecedent basis and would raise 35 USC 122, second, paragraph issues. The amendments contain containing new proposed limitations to the fusion protein do not have literal support nor specific figurative support toward the broad embodiment in the instant specification, and raise issues of new matter. Further, the previous claims encompassed a fusion polypeptide, and no clear link of how or what was comprised within said polypeptide fusion protein. The new structural limitations would require a new search and further consideration.

Section 6(c):

Applicants arguments directed to the obviousness of the invention encompassing a specific single fusion HPV protein in the combination of Donnelly *et al.* and Johnson references alone is convincing. Specifically, while each reference teaches that multiple epitopes or multi-valent responses could be used in DNA vaccines, Examiner agrees that the generation of one polypeptide containing multiple domains is not specifically taught in either reference. However, the instant claims can fairly be interpreted to encompass fusion proteins of the ORFs or fragments thereof. A ‘fusion polypeptide’ is *referred* to as polypeptides which ‘can be present in any combination’(page 5; last full paragraph), however it does not require that a fusion protein contain both L- and E-ORFs. In addition, Applicants’ arguments directed to the subsequent

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rejections which include specific teaching of multi-epitope fusion proteins, such as Whittle *et al.*, Stanley *et al.* and Gissmann *et al.* is not found convincing. Donnelly *et al.* is relied upon for the teaching that multiple epitopes of HPV can be used in DNA vaccines. Each Donnelly *et al.* and Johnson acknowledge the same limitations of known vectors taught in the art for DNA vaccines, and Johnson is relied upon for the teaching of an improved vector system, rAAV vectors, for the delivery and expression of a gene of interest, in particular for use in DNA vaccines. Whittle *et al.*, Stanley *et al.* and Gissmann *et al.* clearly teach that fusion proteins could be generated from recombinant vectors, and Whittle *et al.* and Stanley *et al.* specifically teach that they can be used in immunotherapeutic methods. In view of the art as a whole, it is maintained that the combination of the teachings in the cited references as a whole provide adequate motivation and guidance which makes obvious the instantly claimed products.